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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/687,846      | 10/17/2003  | Yelena Nabutovsky    | A03P3002-US1        | 9561             |

24473 7590 04/10/2006

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| EXAMINER |
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FLORY, CHRISTOPHER A

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

3762

DATE MAILED: 04/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |   |   |  |
|------------------------------|---|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/687,846    | <b>Applicant(s)</b><br>NABUTOVSKY, YELENA |  |
|                              | <b>Examiner</b><br>Christopher A. Flory | <b>Art Unit</b><br>3762                   |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>06 November 2003</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

### ***Specification***

2. The disclosure is objected to because of the following informalities: there is a typographical error in paragraph [0065] which reads " $(|C_{I2} - C_{I1}| \# C_{I_{threshold}})$ " which should be corrected to read " $(|C_{I2} - C_{I1}| < C_{I_{threshold}})$ "—in context with the rest of the paragraph.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claims 1-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Stoop et al. (US Patent 6,370,431).

Regarding claims 1-12 and 23-28, Stoop et al. discloses a method of detecting and preventing ventricular arrhythmias comprising detecting at least two PVCs, determining a difference between their morphologies, and comparing said morphology difference to a predetermined threshold to determine whether to deliver preventative therapy (column 2, lines 10-50); further comprising a step of determining a difference between the coupling intervals of the at least two PVCs and comparing the difference to a predetermined threshold to determine whether to deliver preventative therapy (column 9, line 47 through column 10, line 10); further comprising a step of adjusting the threshold values based on recently detected physiological events (column 5, line 45 through column 7, line 59; column 10, lines 48-54); and delivering preventative therapy in the form of overdrive pacing when the analysis of the PVC parameters indicates that therapy should be delivered (column 2, lines 42-50; column 10, lines 11-54).

Further regarding claims 9 and 10, Stoop et al. states the coupling interval as referring to "the interval from the prior R wave to the VES to the current QT interval," (column 9, lines 60-62) where the term QT "embraces both the QRS portion and T wave portion of the ventricular signal" (column 3, lines 60-63). It is understood that this is a disclosure of R-R coupling intervals. However, as seen in Fig. 1 the disclosed device of Stoop et al. also comprises P-wave sense circuitry (25) and, so long as the definition of coupling interval remains consistent, would be capable of using P-R intervals instead of the stated R-R intervals for a functional equivalent result well known in the art.

Further regarding claim 11, Stoop et al. discloses a method for obtaining depolarization information for the current cycle and comparing it to the template generated during the learning phase which involves compiling values of the QT dispersion in different rate bins and determining the difference of respective wave form amplitudes along successive time increments by subtracting amplitude values and integrating over the time domain (column 5, line 66 through column 6, line 17). It is well known that the time integral of a curve in the Cartesian plane is the mathematical equivalent to the area under said curve, and a subtraction of the time integral of one curve (e.g. the current QRS waveform) from that of another (e.g. a stored template) is representative of the difference of the areas under those curves. Therefore, Stoop et al. is understood to disclose a method of analyzing the morphology of the current QRS complex with a previously stored template (which is based on at least 2 previous measurements) by means of comparing the difference in areas under the current waveform and stored template (Figs. 4A-D and 5A-D). Stoop et al. further discloses weighting the results obtained for use in the subsequent determination of intervention (column 9, lines 20-46; column 10, lines 11-34), which is taken to be an equivalent step to assigning a match score that is proportional to the difference in areas under the compared QRS curves.

Regarding claims 13-22, Stoop et al. discloses an apparatus (Fig. 1, pacemaker system) configured to detect and prevent ventricular arrhythmias comprising a detecting means or sensing circuit (sense circuits 24-26) for detecting at least two PVCs; a processing means (signal processor 27, control microprocessor 20)) for determining

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morphological and coupling interval differences; a comparing means to compare said differences to predetermined thresholds; and a delivery means or pacing circuit (ventricular and atrial pulse generators 15 and 18) for delivering preventative therapy based on said comparisons. (Column 4, lines 7-41).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory

  
George Manuel  
Primary Examiner